

1984 SEP 17 AM 11:32

OCT 25, 1983  
02 25 00

Stephen Kurzman, P.C.  
Nixon, Hargrave, Devans and Doyle  
1090 Vermont Avenue, N. W. (Suite 1200)  
Washington, DC 20005

RE: Docket No. 81N-0022/CP0004, CP0005 and  
Docket No. 76N-0052N/CP0004, CP0005

Dear Mr. Kurzman:

This is in reply to the citizen petitions submitted to the Food and Drug Administration on September 26, 1983, and October 13, 1983, requesting that the administrative records for the OTC weight control drug products and the OTC nasal decongestant drug products rulemakings be reopened to include new data and information on phenylpropanolamine hydrochloride.

The agency has decided to include the data in question in the administrative records for the rulemakings for OTC weight control drug products and OTC nasal decongestant drug products. In the advance notice of proposed rulemaking for OTC weight control drug products, published in the FEDERAL REGISTER of February 26, 1982 (47 FR 8466), the agency stated that it would continue to monitor further studies and information on phenylpropanolamine. The data accompanying your petitions provide additional information regarding the safety of phenylpropanolamine hydrochloride and is currently being reviewed in conjunction with the development of the tentative final monographs (TFM) for OTC weight control drug products and OTC nasal decongestant drug products. The agency considers your petitions to be "feedback" communications.

In the FEDERAL REGISTER of September 29, 1981 (46 FR 47740), announcing the "feedback" policy, the agency stated that "feedback" communications would not be included in the administrative record for the related OTC monograph unless the communication directly influences an agency decision on a particular matter in the monograph or provides the substantiation for the agency's decision on that matter. We also stated that the results of a study would be included when they were one of the bases for the Commissioner's decision on an ingredient. This feedback policy was further clarified in the FEDERAL REGISTER of April 1, 1983 (48 FR 14050). Because the data accompanying your petitions will be used by the agency in reaching a decision on the classification of phenylpropanolamine hydrochloride in the respective TFMs, the agency is including it in the appropriate administrative records at this time.

76N-052N

PAN002

Stephen Kurzman, P.C.

Page 2

Should you have any questions regarding this matter, please refer to the appropriate Docket Numbers above and submit the inquiry in triplicate to the following address:

Dockets Management Branch  
Food and Drug Administration  
Room 4-62  
5600 Fishers Lane  
Rockville, MD 20857

Sincerely yours,

William E. Gilbertson, Pharm. D.  
Director  
Division of OTC Drug Evaluation  
Office of Drug Standards  
National Center for Drugs and Biologics

cc: HF-1 HFY-1 HF-40  
HF-2 HFW-1  
HF-43 (8302891)  
GCF-1 (2)  
HFA-224  
HFA-305 (Docket Nos. 81N-0022 and 76N-0052N)  
HFC-1  
HFC-2  
HFC-10  
HFN-1  
HFN 7  
HFN-200  
HFN-500  
HFN-510: ING 40.33 DDC 980.3/DDC 370.3/Reading/Deputy  
HFN-513: Reading/Eader/Cothran  
HFN-514: Reading/Myers/Short  
RD: JShort/10/13/83/lj/10/13/83  
END: DMyers/10/14/83  
END: GTrosclair/10/17/83  
FINAL: ljones/10/18/83  
DOC ID 0240J/DISKETTE 079C

*Short* 10/18/83  
*Short* 10/24/83  
*DMyers* 10/18/83  
*gm* 10-25-83